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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,659	10/25/2001	Pamela A. Kramer	ACS-54306(22571)	6167

24201 7590 02/18/2004

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EXAMINER
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HO, UYEN T

ART UNIT	PAPER NUMBER
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DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/032,659

Applicant(s)

KRAMER ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 12, 17-21 and 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-16 and 22-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4, 6.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-29, drawn to medical device, classified in class 623, subclass 1.15.
  - II. Claims 30-40, drawn to method of manufacturing a fine-grained medical device, classified in class 427, subclass 2.24.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the process as claimed can be used to make other and materially different product such as bone screw, implant or a medical product other than stent, filter, catheter, guidewire and leadwire.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. This application contains claims directed to the following patentably distinct species of the claimed invention: Species 1: Stent (claims 14-16, 22-29); Species 2: Filter (claim 17); Species 3: graft (claim 18); Species 4: guidewire (claim 19); Species 5:

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wirelead (claim 20); Species 6: catheter (claim 21) and Subspecies 1: hypotube (claim 11); Subspecies 2: a wire (claim 12).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. During a telephone conversation with Ronald E. Perez on 2/12/2004 a provisional election was made without traverse to prosecute the invention of Group I, Species 1, Subspecies 1, claims 1-11, 13-16, 22-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12, 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

7. The information disclosure statement (IDS) submitted on 10/7/2002 and 1/6/2003 have considered and placed in the application.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3, 7, 9, 10, 11, 13, 14, 22, 26-29 are rejected under 35 U.S.C. 102(e) as being ant by Whitcher et al. (US 2003/0018381 A1). Whitcher et al. disclose a stent as claimed wherein the stent is made from a substrate having a grain size of less than twenty microns (figures 2-4, paragraph 0042 and 0062).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2, 4-6, 8, 15, 16, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcher et al. (2003/0018381 A1).

In regard to the grain size as claimed, Whitcher et al. indicate conventional grain sizes are on the order of 10 microns or larger and Whitcher et al.'s stent being made from a substrate less than 1 microns. Although, Whitcher et al. do not disclose the grain size of the substrate in range of one to ten microns, it would have been obvious matter of design choice since the applicant has not disclosed that having the grains size in the range of 1-10 microns solves any stated problem or is for any particular purpose and it appears that the stent would perform equally well with the substrate having grain size from 1-10 microns of from 1-500 nanometers or at the conventional grain sizes of 10 microns or little larger.

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In regard to the material of the substrate as claimed, although, Whitcher et al. do not disclose a stent being made from 316L stainless steel, cobalt-chromium or platinum-irridium alloy, the material as claimed are known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make Whitcher et al.'s stent from the materials as claimed wherein so doing would amount to mere substitution of one material for an other within the same art that would perform equally well in Whitcher et al.'s stent.

In regard to the number of grains across a strut thickness, Whitcher et al. do not disclose the number of grains across a strut thickness is in the range of five to fifteen, it is known in the art to make stents having different thickness to accommodate and support the vessel. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make stents having struts of varying thickness in order to accommodate and support the vessel. Doing so would make at least a stent having the number of grains across a strut thickness is in the range of five to fifteen in order to accommodate and support a vessel wall at a size required a stent in that specific thickness.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731  
February 14, 2004